

REMARKS

**35 USC Section 112, second paragraph**

Claim 25 is rejected under 35 USC Section 112, second paragraph as being indefinite.

In order to expedite prosecution, claim 25 is amended herein to refer to "huMAb4D5-8" as supported on page 10, line 25, for example, thus obviating the rejection. Reconsideration and withdrawal of the Section 112, second paragraph rejection is respectfully requested.

**35 USC Section 103**

Claims 21, 25 and 26 are rejected under 35 USC Section 103 as being unpatentable over any Baselga et al. *J. Clin. Oncol.* 14(3): 737-744 (1996) ("Baselga I"), or Baselga et al. *Semin. Oncol.* 4(12): 78-83 (1999) ("Baselga II") in view of Pauletti et al. *Oncogene* 13: 63-72 (1996), or Persons et al. *Annals. Of Clinical and Laboratory Science* 30(1):41-48 (2000).

Claim 1 is amended herein to refer to state that the "patient's tumor cells express HER2 at a 0 or 1+ level by immunohistochemistry" as supported, for example, on page 28, lines 27-29.

The present invention provides an improved method for screening for, and treating, breast cancer patients, wherein patients with her2 gene amplification are treated with a HER2 antibody. This method is not disclosed or suggested by the cited references. Baselga I and Baselga II describe therapy of patients whose metastatic breast carcinomas overexpress HER2 as determined by IHC (see *Selection of Patients* in column 1 on page 738 of Baselga I, and *Patients* in columns 1-2 on page 79, Baselga II). Pauletti concerns FISH for clinical prognosis (abstract of Pauletti), and Persons studied HER2 amplification as a prognostic and predictive marker (summary paragraph in column 2 on page 47 of Persons), rather than detecting her2 gene amplification in tumor cells in order to identify and treat a patient disposed to respond favorably to a HER2 antibody.

Applicants submit that the presently claimed invention and its unexpected advantages for better selecting patients who can benefit from therapy with a HER2 antibody are neither disclosed nor suggested in the cited art. Reconsideration

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and withdrawal of the Section 103 rejection is respectfully requested.

**IDSs**

Applicants note that initialed copies of the PTO 1449 forms from the July 21, 2003 IDS (citing ref. No. 319) and August 20, 2004 IDS (citing ref. Nos. 320-349) had not been returned to them. Examiner Holleran said at the interview that a copy of the August 2004 IDS was in the PTO's file, but she could not locate a copy of the PTO-1449 or reference from the July 2003 IDS. Accordingly, Applicants attach a courtesy copy of the 2003 IDS, PTO-1449 form and cited reference for the Examiner's convenience. Applicants respectfully request that the initialed PTO 1449 forms be returned, completing the Office's review of all cited art.

Respectfully submitted,  
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